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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,053	11/03/2003	Anna Gutowska	23-66882	5500

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EXAMINER

JONES, DAMERON

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/701,053

Applicant(s)

GUTOWSKA ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/22/04; 12/2/04; & 1/6/05.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-68 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 59-68 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/22/04; 12/2/04; & 1/6/05
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

1. The Applicant's arguments filed 12/2/04 to the rejection of claims 59-68 made by the Examiner under 35 USC 103, 112, and/or double patenting has been fully considered and deemed persuasive-in-part.

Note: Claims 59-68 are pending.

Statutory Double Patenting

The rejection of claims 64-68 under 35 USC 101 as claiming the same invention as that of claims 10-17 of prior US Patent No. 6,660,247 is MAINTAINED for reasons of record.

It is duly noted that Applicant asserts that since all the limitations are not in the claim, a statutory double patenting does not exist.

Applicant is reminded that patentability of a product is based upon the components of the product, not the use of the product. Thus, stated in the previous office action, the claims are the same because both are directed to a polymeric compound comprising a polymeric solution. The intended use of the compound is not given patentable weight for the product. Hence, what happens to the product once it undergoes the transformation is not the same product that was initially present. It appears as if Applicant is basing patentability on the gel being formed at the various conditions, and not the components of the initial product.

Obviousness-type Double Patenting

The rejection of claims 59-63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-31 of US Patent No. 6,660,247 is MAINTAINED for reasons of record.

Applicant asserts that the patented claims are directed to sterilization as set forth in the instant invention.

While the patented claims do not specifically state that they encompass sterilization, a skilled practitioner in the art would recognize that the patented claims encompass sterilization because the composition may be injected to achieve therapeutic embolization (see claim 23, column 12) and column 4 of the patent discloses that the polymeric solution may be either a carrier for a pharmaceutically active therapeutic agent or act as an inert blocking mass. Furthermore, it discloses that the inert blocking mass results from gelled mass restricting a tube of the body and as examples, an aneurism of a blood vessel or vas deferens for purposes of reversible sterilization in males are disclosed as reasons for the inert blocking mass. Thus, claim 22 which discloses that the composition is injected into a specific locus and claim 23 in combination with what is taught in Applicant's disclosure indicate that sterilization is encompassed in the patented claims.

112 First Paragraph Rejection

The rejection of claims 59-68 under 35 USC 112, first paragraph, because the specification, while being enabling for the composition comprising a methacrylamide

derivative and a hydrophilic co-monomer as, does not reasonably provide enable for all polymeric compounds is MAINTAINED for reasons of record.

Applicant asserts that genus claims are typically enabled if the disclosure include representative polymeric examples which are linked by the fact that they gel only upon exposure to critical minimum values of at least two environmental stimuli.

First, Applicant is reminded that some of the claims are directed to products and patentability of a product is based upon the components of the product, not the use of conditions that the product undergo. Secondly, the specification is limited to the compositions as set forth in the previous office action. As a result, Applicant's arguments are not found persuasive because it is not clear that Applicant had possession and knowledge of the various polymeric compositions that may be used for sterilization or gelled based on the disclosure. Hence, the specification has not clearly set forth what compositions the invention actually had possession and knowledge. What Applicant has disclosed is merely a plan to accomplish an intended result (i.e., gelation occurs and a subject is sterilized). Thirdly, while the claims call for polymeric compounds/compositions, the specification only identifies a limited number of compounds/compositions. As a result, in order to perform the instant invention, one must engage in a trial and error process since the polymer compound/composition is being described in terms of its function (i.e., gelation occurring based on various stimuli). Therefore, the level of one of ordinary skill in the art is high in determining the boundaries of the instant invention, the level of predictability is high since various polymer combinations and condition would have to be analyze. Overall, a person of

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ordinary skill in the art would be forced to engage in undue experimentation since guidance is lacking and the working examples are limited while the breadth of the claims is extremely broad. It is also noted that the claim depends upon the user finding the appropriate stimuli and polymeric compound/composition combination.

112 Second Paragraph Rejection

The 112 second paragraph rejections are WITHDRAWN.

103 Rejection

The rejection of claims 64, 65, 67, and 68 under 35 USC 10-3(a) as being unpatentable over Goupil et al (US Patent No. 6,652,883) is MAINTAINED for reasons of record.

Applicant asserts that the patent fails to disclose gellation.

Applicant is once again reminded that patentability of a product is based on the components of the product, not the intended use of that product. However, intended use does carry patentable weight in a method claim. As a result, since both the instant invention and that of Goupil et al disclose polymeric compounds wherein the aqueous polymeric solutions are exposed to a stimuli and the formation of a hydrogel may occur, a skilled practitioner would recognize that the transformation of the solution to a hydrogel resulting from the stimuli is the same as what occurs in the instant invention.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within


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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
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March 7, 2005